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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,836	02/04/2002	Keith Biggadeke	PG4739	6053

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/26/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/066,836

Applicant(s)

BIGGADIKE, KEITH

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____ .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/067,020.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6 & 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

First Office Action on the Merits

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-8 and 10-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 10/067,020. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α -(2-furanylcabanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions. The latter application, unlike the present application, is limited to an aqueous suspension. Compositions for delivery by inhalation as recited by the instant claims may be formulated as aqueous suspension (see page 6, lines 14-17 of the present application). The instant claims also recite a composition comprising the claimed compound and a β_2 -adrenoreceptor agonist for treatment of respiratory disorders over a period of 24

hours or more. The claimed aqueous suspension of the latter application can also be (a) utilized for treatment of respiratory disorders over a period of 24 hours or more (see page 10, lines 16-19 of the latter application) and (b) administered in combination with other therapeutic agents (see page 10, line 21 – page 11, line 3 of the latter application). Thus, the claimed composition of the latter application is encompassed by the instantly claimed composition.

3. Claims 1-7 and 10-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 10/066,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α -(2-furanylcabanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions. The latter application, unlike the present application, is limited to an aerosol formulation. Compositions for delivery by inhalation as recited by the instant claims may be formulated as aerosols (see page 9, lines 4-11 of the present application). The instant claims also recite a composition comprising the claimed compound and a β_2 -adrenoreceptor agonist for treatment of respiratory disorders over a period of 24 hours or more. The claimed aerosol formulation of the latter application can also be utilized for treatment of respiratory disorders over a period of 24 hours or more and administered in combination with other therapeutic agents, such as β_2 -adrenoreceptor agonist (see page 12, lines 1-12 of the latter application). Thus, the claimed

composition of the latter application is encompassed by the instantly claimed composition.

4. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 10/200,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α -(2-furanylcabanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions. The latter application, unlike the present application, is limited to a composition comprising a crystalline form of the 17α -(2-furanylcabanoyloxy) ester of fluticasone. The instantly claimed formulation encompasses crystalline forms of the 17α -(2-furanylcabanoyloxy) ester of fluticasone stabilized by formation of salts with bases such as triethylamine (see for example page 7, lines 15-27; page 15, line 9 – page 17, line 26; page 21, line 32 - page 22, line 3 of the present application). The instant claims also recite a composition comprising the claimed compound and a β_2 -adrenoreceptor agonist for treatment of respiratory disorders over a period of 24 hours or more. The claimed crystalline formulation of the latter application can also be utilized for treatment of respiratory disorders over a period of 24 hours or more and administered in combination with other therapeutic agents, such as β_2 -adrenoreceptor agonist (see page 13, lines 4-14 of the latter application). Thus, the claimed composition of the latter application is encompassed by the instantly claimed composition.

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5. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 10/241,658. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compositions comprising the 17α -(2-furanylcabanoyloxy) ester of fluticasone. The difference between the two applications is based on the scope of the claimed compositions. The latter application, unlike the present application, is limited to a composition comprising a crystalline form of the 17α -(2-furanylcabanoyloxy) ester of fluticasone. The instantly claimed formulation encompasses crystalline forms of the 17α -(2-furanylcabanoyloxy) ester of fluticasone (see for example page 7, lines 15-27; page 15, line 9 – page 17, line 26; page 21, line 32 - page 22, line 3 of the present application). The instant claims also recite a composition comprising the claimed compound and a β_2 -adrenoreceptor agonist for treatment of respiratory disorders over a period of 24 hours or more. The claimed crystalline formulation of the latter application can also be utilized for treatment of respiratory disorders over a period of 24 hours or more and administered in combination with other therapeutic agents, such as β_2 -adrenoreceptor agonist (see page 13, lines 4-14 of the latter application). Thus, the claimed composition of the latter application is encompassed by the instantly claimed composition.


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T I phone Inquiry

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
September 24, 2003